

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Pamela M. Drake
Application No. : 10/763,570
Filed : January 23, 2004
For : COMPOSITIONS AND METHODS FOR RESTORING
BACTERIAL FLORA

Examiner : Lora E. Barnhart
Art Unit : 1651
Docket No. : 340082.401

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF PAMELA M. DRAKE
PURSUANT TO 37 CFR § 1.131

Commissioner for Patents:

I, **Pamela M. Drake**, declare as follows:

1. I, **Pamela M. Drake**, am the inventor of the subject matter disclosed and claimed in the above-referenced patent application ("the subject application").

2. I provide this Declaration for the purpose of demonstrating that the presently claimed invention was conceived of and reduced to practice prior to the October 11, 2002, international filing date of Wynne *et al.* (WO 03/033681), and, in fact, prior to the October 12, 2001, priority date of Wynne *et al.*, which was cited by the Examiner as the primary reference in a rejection of claims 1, 2, 5, and 7 under 35 U.S.C. § 103(a). The work described in this Declaration and in the attached Exhibits was performed in the United States by myself or by others, with my knowledge and under my direction.

3. I herewith submit a copy of a product description document titled "FLORA TECHNOLOGY PRODUCT DESCRIPTION," which summarizes and describes several product kits developed by myself or by others, with my knowledge and under my direction (Exhibit 1). Specifically, this document describes kits developed for oral administration comprising the following: (i) isolated or purified bacteria; (ii) nutrients for the isolated or purified bacteria, including spirulina, fructooligosaccharides, and methylsulfonylmethane; (iii) an anti-fungal agent; and (iv) ascorbic acid. This document was prepared prior to September 1, 2001. Thus, this document demonstrates that I had possession of and had diligently reduced to practice the invention prior to October 12, 2002. Furthermore, the invention was promptly disclosed to our patent counsel, who diligently prepared and filed the subject application.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information or belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the captioned patent application or any patent issued therefrom.

3/15/08
Date

Pamela M. Drake
Pamela M. Drake

FLORA TECHNOLOGY PRODUCT DESCRIPTION

The Uniqueness of our Kits:

The kits serve as a rebuilding, restorative measure to damaged gut-flora and can be considered an inoculation kit or prophylactic since most people have, at some time in their lives, used antibiotics and as a consequence, need rebuilding of the gut flora. They contain the food supply the friendly bacteria need for proper implantation: Spirulina, MSM, and Fructooligosaccharides. Though each of the many probiotic products on the market have their own benefits, they are ineffective because they are not combined with a weed killer like Nystatin which kills the yeast that would otherwise control the whole gut eco system.

To our knowledge, no one has put together a prescription and non-prescription item in the same box. The uniqueness, therefore, is in the packaging and symbiotic relationship of prescription and non-prescription. The two items act somewhat like a weed-and-feed team. The prescription, Nystatin, is in a separate bottle and stands on its own as a 1st generation anti fungal and is readily available. Nystatin has relatively few side effects and is widely used for yeast overgrowth, which follows the use of antibiotics and chemotherapy. The Nystatin is used in The Standard Kit, Colon Care Kit, and the Super-Immuno Kit. When perscribed by a medical professional, Nystatin is also available in the Infant Kits.

All kits contain Lactobacillus Acidophilus in the form of DDS-1 strain. DDS-1 is a 2nd generation strain of Lactobacillus Acidophilus that is more stable and has greater resilience and success in implantation than 1st generation strains. This particular bacteria appears to be destroyed in greater number due to antibiotic use, chemotherapy, alcohol, and antibiotic-laden food such as meat, milk, and pears.

It is interesting to note that a large percentage of the worldwide population does not have the needed delicate balance of friendly bacteria in the gut flora. Consequently rampant cases of E. Coli and super germ mutations may thrive. Immune-compromised individuals are at higher risk of the development of super germs or other resistant bacteria.

Highlights of Our Kits:

1. Each kit comes with an prescription anti-fungal, separate but in the same box.
2. The bacteria are all human strain. Animal strain bacteria is the most readily available on the market, however, human strain is the most viable and virulent for implantation in the human gut. Currently most yogurts and milk products that utilize friendly bacteria utilize that of an animal strain.
3. Where available, the friendly bacteria are at least 2nd generation strain.

4. The bacteria are separated from their medium by filtration, not centrifugation, allowing for the more viable bacteria and stronger organism
5. The bacteria are packaged with their own food supply to ensure a growth medium - the food supply being Fructooligosaccharides, spirulina, Ascorbic acid and MSM (Methylsulfonylmethane).
6. The bacteria are specific for certain disease processes as outlined in many medical studies. *Examples: Bifidophilus longum is shown to be effective in preventing bowel cancer; Certain lactobacillus strains have reduced the reoccurrence of urinary tract infections. Bacillus laterosporus produces metabolites with antibiotic, anti-tumor and immune modulating activity. A proper balance of probiotics has been found to help prevent clostridium difficile, a common diarrheal condition.*
7. These kits can be used prophylactic or as an inoculation against the super germ since much of one's immune modulating response takes place in the gut flora.
8. All kits may be similarly used for veterinary use. At least fifty percent of all antibiotics used in the world are used in animals.
9. The new ingredient MSM is used.

Types of Kits:

There are 8 human kits and 8 veterinarian kits at this time, each kit being different according to it's unique combination of bacteria or route of administration.

Kit 1 Standard Post-Antibiotic Kit:

This kit is recommended for anyone who is on an antibiotic. The kit should be used during antibiotic use and a minimum of 30 days after discontinuation of the prescribed antibiotic. It is recommended to be taken between meals and separately from the antibiotic as prescribed by a medical professional.

This kit is formulated by the following method:

Step 1 - Combine the following friendly bacteria; Lactobacillus Acidophilus, Lactobacillus Bulgaricus and Streptococcus Thermophilus.

Step 2 - Spirulina, and Fructooligosaccharides are added to the formula as a food substance. Studies have shown that substances such as these are

more bio available and easily assimilated by the friendly bacteria as a food for growth and verilance. Because of our eating habits and food processing methods these food substances are not available in a high enough concentration.

Step 3 - Add ascorbic acid to MSM (Methylsulfonylmethane). MSM is a form of sulfur which comprises the 3rd largest ingredient in every human cell. These two substances work together symbiotically for proper utilization in the body and also fortify the friendly bacteria.

Step 4 - The MSM mixture is then added to the formula.

Step 5 - This is then encapsulated in vegetarian gel capsules.

Kit 2 *The Colon Care Kit 2:*

This kit is recommended for diarrheal diseases, irritable bowel, cancer, diverticulitis, ostomies, ulcers, ulcerative colitis, and/or any bowel disorder or flu.

This kit is formulated by the following method:

Step 1 - Combine the following friendly bacteria; *Lactobacillus Acidophilus*, *Streptococcus Thermophilis*, *Lactobacillus Bulgaricus*, *Bifodophilus Longum*, *Bifido bacteria Bifidus*, and *Bacillus Laterospous*.

Step 2 - *Spirilina*, and *Fructoologosaccrides* are added to the forumla as a food substance.

Step 3 - Add ascorbic acid to MSM (Methylsulfonylmethane

Step 4 - The MSM mixture is then added to the formula.

Step 5 - This is then encapsulated in vegetarian gel capsules.

Kit 3 *Super-Immuno Kit 3:*

This kit is recommended for Aids, cancer, high cholesterol, chronic disease of any kind, and any immune-compromising disease of a serious nature. This kit contains the broadest spectrum of bacteria, but the process is the same.

This kit is formulated by the following method:

Step 1 - Combine the following friendly bacteria; *Lactobacillus Acidophilus*, *Bacillus Bifidum*, *Lactobacillus Bulgaricus*, *Lactobacillus plantarium*, *Lactobacillus Rueteri*, *Streptococcus Thermophilis*, *Lactobacillus Salivarius*, and *Bifidobacteria Bifidus*.